
APPLICATION FOR UNITED STATES LETTERS PATENT

for

**CHRONIC PAIN PATIENT RISK STRATIFICATION
SYSTEM**

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CHRONIC PAIN PATIENT RISK STRATIFICATION SYSTEM

This application claims the benefit of provisional application U.S. Serial No. 60/258,556 filed on December 29, 2000 entitled "Disease Management System And Methods" by Goetzke et al. This application is also related to the following co-pending applications entitled "Chronic Pain Patient Identification System" by inventors Goetzke et al. (attorney docket number P9581.00); "Chronic Pain Patient Diagnosis System" by inventors Goetzke et al. (attorney docket number P9641.00); "Chronic Pain Patient Medical Resources Forecaster" by inventors Goetzke et al. (attorney docket number P9642.00); "Chronic Pain Patient Care Plan" by inventors Goetzke et al. (attorney docket number P9643.00) which are not admitted as prior art with respect to the present invention by its mention in this cross reference section.

BACKGROUND OF THE INVENTION

This disclosure relates to a medical information system and more specifically to a chronic pain patient risk stratification computer program and method.

Although medical treatment of acute injuries and illnesses have improved significantly over the past few decades, chronic disease remains by far the greatest cause of mortality, diminished quality of life, and increased healthcare expenditures. Approximately 80% of healthcare costs are spent on the treatment of chronic disease, much of it on unnecessary hospitalizations, inappropriate medical interventions, and poor overall coordination of care. This is true because chronic diseases are commonly treated but quite frequently not appropriately managed. The bulk of these expenses are spent on cardiovascular disease, cancer, diabetes, AIDS, orthopedic and spinal disease, arthritis, and the full range of neurological diseases. In countries with an aging population, the prevalence of chronic disease will increase dramatically, further accentuating the need for better chronic care.

Historically chronic disease has often been considered part of normal aging with little attention given to prevention, precise diagnosis and fully coordinated, long-term treatment. This view of chronic disease manifests itself with relatively late-stage treatments conducted as a series of acute interventions after a critical episode. Treatments after a critical episode are typically more invasive, expensive, and less effective at restoring an individual to a full health than treatments that could be given prior to episode if only the chronic disease risk or symptoms had been more accurately diagnosed. The medical profession's focus on late-stage treatment of chronic disease after a series of acute interventions has been influenced by the compartmentalization of medical specialties around acute diseases that often do not provide optimal treatment for chronic diseases. The medical profession's lack of attention to chronic disease has also been slow to change because of the largely passive role payers, employers, health care policy makers and patients have played in the past.

The medical profession's perspective on chronic disease is changing through increased knowledge and access to better data and more meaningful information that are changing historical views. Adding momentum to the medical profession's understanding of chronic disease is the empowerment of payers and patients. Payers are pressuring the medical profession to control the high cost of chronic disease treatment. Payers understand that chronic disease costs can often be substantially reduced through a better understanding of chronic disease risks, early and accurate diagnosis, appropriate intervention, and fully coordinated, long-term care. Patients are empowered with informational technologies to ask questions, understand disease risks and symptoms, understand alternatives including complimentary therapies, and seek treatments that improve both length and quality of life.

With the change in focus on chronic disease, there is recognition that the following chronic diseases that are not effectively managed: cancer, cardiovascular diseases, neurological diseases, musculo-skeletal diseases, diabetes, gastro-intestinal diseases, and chronic pain. The chronic pain population is among the most difficult to identify, to accurately diagnose, and to manage.

Many primary care physicians have limited knowledge of the broad spectrum and varied etiologies of chronic pain. Primary care physicians also have a limited understanding of the medical and non-medical risks associated with later onset of chronic pain. This lack of understanding often results in their inability to identify patients at risk of chronic pain and to appropriately stratify these patients in a manner that is responsive to the patient's health care needs, both immediately and over the course of the patient's disease state.

Just recently chronic pain has begun to be recognized as a separate chronic disease deserving its own plan of treatment. The complexity of chronic pain disease is described in texts such as Merskey et al., "Classification Of Chronic Pain, 2nd Ed.", International Association For The Study Of Pain, IASP Press (1994). Chronic pain has many causes. For example, chronic pain is an attendant syndrome with hereditary or degenerative diseases such as diabetes, Huntington's Disease and hereditary ataxia. It can be the direct result of trauma, such as a head injury or broken limb. Or, it can be the result of something more insidious and less intuitive, such as the pain syndromes known as phantom limb pain, stump pain and pain of general psychological origin. It is because chronic pain is multi-dimensional and non-homogenous that the identification, stratification, diagnostic, treatment, and cost forecasting processes have lacked uniformity, consistency and predictability - reasons that have contributed to costly, in-efficient and sometimes in-effective care.

Previous clinical efforts have not effectively identified patients who are at risk for chronic disease, who have undetected chronic disease, or who have been misdiagnosed for a condition other than their actual chronic disease.

Previous clinical efforts have been particularly ineffective in stratifying potential chronic pain for risk, so they are treated appropriately and expeditiously, and in a manner that corresponds to their disease condition.

For the foregoing reasons, there is a need for a chronic disease patient stratification system that permits earlier and more targeted intervention to treat chronic disease to improve patient health, reduce costs, and provide additional benefits.

SUMMARY OF THE INVENTION

The chronic pain patient risk stratification system can be a method or computer software product that stratifies potential chronic pain patients according to risk. Desired patient indicia including direct medical indicia, indirect medical indicia, and non-medical indicia are selected to serve as independent variables. At least one chronic pain indication is selected to serve as a dependent variable. A chronic pain risk model is created using the patient indicia and the chronic pain indication. The chronic pain risk model is applied to potential chronic pain patients that have been selected from a population that conform to the chronic pain model. Some embodiments can include establishing selection preferences that specify patient characteristics desired to be selected by a stakeholder such as a patient, primary care physician, specialist physician, employer, or payer. The selection preferences are calculated with each potential chronic pain patient's mathematical expression to identify relationships between the selection preferences and each potential chronic pain patient's mathematical expression. Each potential chronic pain patient is categorized based upon the relationships between the selection preferences

and each potential chronic pain patient's mathematical expression. Some embodiments can include sensitivity analysis to improve accuracy of the chronic pain patient risk stratification system. The sensitivity analysis includes comparing the identified chronic pain patients with outside patient indicia to create a patient error list. An error assessment model is applied to the patient error list to identify the non-corresponding patient indicia that contributed to the errors. A sensitivity analysis model is applied to the non-corresponding to the non-corresponding patient indicia to identify potential patient indicia changes to reduce errors in identifying chronic pain patients. At least one patient indicia change is selected from the potential patient indicia changes to apply to the patient indicia to modify the patient indicia. Many different embodiments of the chronic pain patient risk stratification system method and software product are possible.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a block diagram of a chronic pain patient management system embodiment;
FIG. 2 shows a block diagram of a chronic pain patient identification system embodiment;
FIG. 3 shows another block diagram of a chronic pain patient identification system embodiment;
FIG. 4 shows a more detailed block diagram of a chronic pain patient identification system embodiment;
FIGS. 5a-5b show a table of direct medical indicia prophetic example embodiment;
FIGS. 6a-6b show a table of direct medical indicia therapeutic agents prophetic example embodiment;
FIGS. 7a-7b show a table of indirect medical indicia prophetic example embodiment;
FIGS. 8a-8b show a table of non-medical indicia prophetic example embodiment;
FIG. 9 shows a block diagram of a chronic pain patient data preparation embodiment;
FIG. 10 shows a block diagram of a chronic pain model development embodiment;

FIG. 11 shows a block diagram of a chronic pain risk stratification levels embodiment;
 FIG. 12 shows a table of some chronic pain risk stratification combinations embodiment;
 FIG. 13 shows a block diagram of some chronic pain risk stratification levels embodiment;
 FIG. 14 shows a Chi-Square Automatic Interaction Detection (CHAID) analysis of harm
 5 reduction (level 1) prophetic example embodiment;
 FIG. 15 shows a Chi-Square Automatic Interaction Detection (CHAID) analysis of pain
 stratification (level 2) prophetic example embodiment;
 FIG. 16 shows a Chi-Square Automatic Interaction Detection (CHAID) analysis of pain
 treatment (level 3) prophetic example embodiment;
 10 FIG. 17 shows a Chi-Square Automatic Interaction Detection (CHAID) analysis of care
 management (level 4) prophetic example embodiment;
 FIG. 18 shows a logistics table prophetic example embodiment;
 FIG. 19 shows a block diagram of applying preferences to a patient mathematical expression;
 FIG. 20 shows a block diagram of a sensitivity analysis chronic pain patient identification system
 15 embodiment; and,
 FIG. 21 shows a more detailed block diagram of a sensitivity analysis chronic pain patient
 identification system embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a block diagram of a chronic medical condition management system
 20 embodiment and some elements of its operating environment. The chronic medical condition
 management system integrates the requirements and interests of at least five stakeholders include
 the patient, employer, payer, medical specialist, primary care physician, and the like. Other
 parties can also be added such as federal government, state government, allied health care

professionals such as chiropractors, physical therapists, occupational therapists, and the like. The chronic medical condition management system can operate on data controlled by each stakeholder and on data contained in a common database. The management system can be operated on a variety of computer systems depending upon the complexity of the management system such as a personal computer, minicomputer, mainframe computer, super computer, and the like. The management system can contain one or more components such as a chronic pain patient identification system, chronic pain patient risk stratification system, chronic pain patient diagnosis system, chronic pain patient dynamic resource forecaster, and chronic pain patient dynamic care plan. All the stakeholders typically desire a health care delivery process that provides appropriate and efficacious care in a cost effective manner, but this desire takes on different meanings depending upon the perspective of the stakeholder. These perspectives are built into the software in the form of categorization preferences, which will later be taken into consideration when making software-driven choices. Since each stakeholder can use system-generated data for different purposes, each stakeholder can have a customized view and access to the data. The system also profiles these data needs as data preferences, and data is provided in accordance with customized data requirement profiles. Following is a brief discussion of each stakeholder's interest.

Employers are typically interested in resource stewardship, maintaining a safe work environment for their workers, enhancing work force productivity, and the like. From an employer's perspective, a safe, healthy, and happy work force translates into improved worker productivity. For this reason many employers strive to understand and meet the basic health care needs of their work force but seek to do so in a cost effective manner. Employers are more engaged than ever in designing benefit packages for their employees. They will typically endorse efficacious, lowest cost treatments

and particularly those designed to promptly return an injured employee to work. To make such benefit decisions, employers need data. Information relating cost benefit analysis and similar data that will allow them to compare therapies based upon clinical effectiveness and cost is very useful. Return to work data is also of critical importance. There is a host of other data points that employers would find useful, but which is data that is not typically collected or well understood. For example, employers would find it helpful to better understand the cost of patient compliance vs. non-compliance with specific treatment options. Information that could profile an employee to predict patient compliance, could be crucial to the decision making process. Also, work environment data, such as knowing whether injury patterns can be identified among a work force, could allow employers to develop targeted strategies to reduce or eliminate work place injuries.

Payers are typically interested in ensuring that clinically effective care is provided to health care members in a cost effective manner that provides a high level of reported patient satisfaction. The role of the payer is evolving with time, and in the future, payers will become more involved in population management for specific disease states. For this reason, payers will require epidemiological data. Payers desire to be more involved in educating their members on specific disease states, personalizing responses to match the specific needs of their members. Additionally, payers require clinical and economic data in a format that business leaders are accustomed to using in the decision making process. In short, payers are evolving their data collection practices to become more practical partners with employers, as both parties strive to tailor benefits to meet the needs of a defined population of employees.

Specialist are typically interested in having patients referred that are appropriate for the specialist scope of practice. Health care payers increasingly demand more rigorous proof of therapy value. The evidence is requested in the form of clinical, quality of life and economic outcome studies,

claims-based retrospective studies, or economic models. Physicians are becoming more involved in the data collection, interpretation and reporting process, and it is quite common for them to develop their own data bank of information on patient outcomes. In addition, the specialist is typically a part of a care team, and the primary care physician usually acts as the gatekeeper of care. Depending upon the primary care physician's approach toward care delivery, the care team is either loosely coordinated or more actively coordinated, or sometime not at all coordinated. However, care coordination is becoming more and more a valued process, as payers and providers are realizing that a seamless and more efficient care process has a direct impact on therapy outcome and cost. For this reason, it is important for the entire team to communicate with each other and to adopt uniform processes for care delivery and outcome reporting. As patients become more actively engaged in the care delivery process, the specialist is also striving to evolve the communication relationship with their patients. Patients are becoming informed consumers of health care services, and specialists are responding by creating new means of communicating with patients. For example, it is quite common for specialists to have their own patient-focused website.

Primary care physicians are typically interested in making a proper diagnosis of their patients and making a proper decision on when a patient should be referred to a specialist. The data and communication needs of the primary care physician are similar to those of a specialist. Additionally, the primary care physician is finding it of practical value to have disease specific information readily available across a broad array of topics. Patients are asking questions that are more detailed about their condition, and often approach physicians with information they pulled from the web relating to a potential therapy or new drug that might be of potential treatment benefit. Being a generalist by training, the primary care physician often finds it useful to easily access clinical summaries, suggested

treatment standards or other similar information that helps them decide how to initiate the management of a condition.

Patients are typically interested in participating in their health care, proper diagnosis of their medical condition, and effective treatment of their medical condition. They are seeking to better understand their medical condition, and to become more actively informed in health care decision-making and more active participants in the treatment process. As more of the payment burden is shifted onto the patient, they also are becoming "care shoppers", and therapy-specific economic data is more relevant to making an informed choice. Patients are also beginning to leverage web technology, using the web to get general disease information as well as to obtain more tailored information, programs or services that are personalized to their medical condition. The web is also being more frequently used as a means of communication between patients and their care providers, and is beginning to take the place of the telephone call and the physician office visit in the care delivery process. One component of the chronic pain patient management system is the chronic pain patient identification system.

FIGS. 2 and 3 show block diagrams of chronic pain patient risk stratification system embodiments, and FIG. 4 shows more detailed block diagram of a chronic pain patient risk stratification system embodiment. The chronic pain patient risk stratification system comprises the general elements of selecting patient indicia to evaluate, selecting a chronic pain indication, creating a chronic pain risk model using the patient indicia and the chronic pain indication, applying the chronic pain risk model to potential chronic pain patients, and stratifying potential chronic pain patients by risk. Additionally, some embodiments can include accessing the chronic pain risk model, applying the chronic pain risk model, establishing categorization preferences for desired categories of stratified potential chronic pain patients, calculating the categorization

preferences with each potential chronic pain patient's mathematical expression to establish relationships, categorizing each stratified potential chronic pain patient based upon these relationships, and monitoring the potential chronic pain patient. The patient indicia are selected from sources such as claims records, medical records, workers' compensation records, and employer records. The chronic pain risk model is applied to potential chronic pain patients identified from a population such as a payer database, employer database, primary care physician database, and the like.

FIGS. 5a-5b show a prophetic table of some direct medical indicia related to chronic pain, and FIGS. 6a-6b show a prophetic table of some direct medical indicia in the form of therapeutic products. Although the indicia in FIGS. 5a-6b are labeled direct medical indicia, under some circumstance certain of these direct indicia could also be classified as indirect indicia. Direct medical indicia associated with chronic pain are selected to serve as independent variables for the chronic pain model. Direct medical indicia include information, recorded by a clinician, relating to a chronic pain indication of a patient. In addition to the direct medical indicia shown in FIGS. 5a-6b, direct medical indicia can also include indicia such as primary diagnosis, associated secondary diagnosis, co-morbidities, drug treatment regimen, telephone consultations with a clinician, trauma episodes, palliative care, rehabilitative care, clinician office visits, emergency room visits, hospitalizations, and the like. Some direct medical indicia can be expressed as codes derived from nationally recognized coding systems such as International Classification of Diseases (ICD), American Medical Association Administrative Current Procedural Terminology (CPT); Healthcare Financing Agency Medical Device Codes (HCPCS), and National Drug Codes (NDC) shown in FIGS. 5a-5b. Direct medical indicia are available from sources such as claims records, medical records, workers' compensation records, employer records, and the like.

The importance of each of direct medical indicia is typically supported by the current body of chronic pain clinical literature, and can also be bolstered by expert medical opinion.

FIGS. 6a-6b show a prophetic table of some of the therapeutic products that can be direct medical indicia. A patient's history of prescription and over the counter drug use can be a primary medical indicator of the existence of chronic pain, and in many cases provides adequate predictive evidence to identify a potential chronic pain patient. The type of drug, as well as the dosing level, and the length of time the patient has been using the drug, are all relevant characteristics in establishing a utilization pattern to support such a classification. Additionally, when certain drugs are used in combination with one another, the predictive power of the drug treatment regimen indicia becomes even more significant. For example, the medical literature indicates that muscle relaxants, anti-inflammatory drugs, anti-depressants, and opioid drugs are commonly prescribed to treat pain patients.

FIGS. 7a-7b show a prophetic table of some indirect medical indicia. Indirect medical indicia associated with chronic pain are selected to serve as independent variables for the chronic pain model. Under some circumstances, the indirect medical indicia could be considered direct medical indicia. Indirect medical indicia include information recorded by a clinician relating to a patient's health condition but non-specific to the disease of chronic pain. Studies support the link between direct and non-medical indicia in predicting the presence of chronic pain. Relevant indicia include such criteria as the patient's mental health status as indicated by a mental health ICD-9-CM diagnosis, as well patient's history of acute respiratory episodes requiring hospitalization or emergency room visits. It is believed that as much as 40% of a back pain patient's overall health care costs can be attributed to mental health treatment, and there is a link between smoking and all chronic disease.

FIGS. 8a-8b show a prophetic table of some non-medical indicia. Non-medical indicia associated with chronic pain are selected to serve as independent variables for the chronic pain model. Non-medical indicia include all indicia related to determining or predicting a person's health care status that is not medical indicia. Less is known in the clinical literature about non-medical indicia as markers for the existence of chronic pain, than is known about medical indicia. Currently known non-medical indicia include socio-demographic factors such as: life style behaviors including alcohol consumption, smoking, weight gain, pain perception factors, life satisfaction measures, patient support structure from the family and the community at large, day time distractions, quality of their marital relationship, and personality and psychological profiles. Additional non-medical indicia include demographic factors such as age, gender, economic status, and race/ethnicity, the existence of an open workers' compensation claim, and the presence of an attorney hired by the patient to adjudicate a workers' compensation claim. Non-medical risk indicia are mined from such sources as medical records; patient self-report documents; patient self-assessment surveys; employer databases; workers' compensation records; medical chart reviews; telephone interviews with patients, treating clinicians, and family members.

Non-medical indicia are routinely used in U.S. state and federal courts by judges and members of a jury to assess whether a plaintive is suffering from a chronic condition such as chronic pain. Although indicia used by judges and juries may be based on personal experience and intuition, some of these non-medical indicia could be considered when preparing a chronic pain model. Some non-medical indicia commonly used in a legal environment include courtroom demeanor, reputation for truth and veracity, demeanor of associates, reputation of counsel, familial persuasion, financial needs, financial expectations, legal experience, personal

injury history, family and friends injury history, cognitive ability, emotional maturity, and media reporting related to the indication.

A chronic pain indication, also known as a chronic pain condition, is selected to serves as a dependent variable for the chronic pain model. Chronic pain indications are published by professional organizations such as the International Association for the Study of Pain (IASP) and include the following indications Peripheral Neuropathy; Stump Pain; Phantom Pain; Complex Regional Pain Syndrome Type I (Reflex Sympathetic Dystrophy); Complex Regional Pain Syndrome Type II (Causalgia); Central Pain; Rheumatoid Arthritis; Osteoarthritis; Sickle Cell Arthropathy; Stiff Man Syndrome; Osteoporosis; Guillain-Barre Syndrome; Superior Pulmonary Sulcus Syndrome (Pancoast Tumor); Pain of Skeletal Metastatic Disease of the Neck, Arm, or Shoulder Girdle; Carcinoma of Thyroid; Post Herpetic Neuralgia; Syphilis (Tabes Dorsalis and Hypertrophic Pachymeningitis); Primary Tumor of a Vertebral Body; Radicular Pain Attributable to a Prolapsed Cervical Disk; Traumatic Avulsion of Nerve Roots; Primary Tumor of a Vertebral Body; Radicular Pain Attributable to a Thoracic Disk; Chemical Irritation of the Brachial Plexus; Traumatic Avulsion of the Brachial Plexus; Postradiation Pain of the Brachial Plexus; Painful Arms and Moving Fingers; Brachial Neuritis (Brachial Neuropathy, Neuralgic Amyotrophy, Parsonage-Turner Syndrome); Raynaud's Disease; Raynaud's Phenomenon; Frostbite and Cold Injury; Brythema Pernio (Chilblains); Acrocyanosis; Livedo Reticularis; Volkmann's Ischemic Contracture; Thromboangiitis; Intermittent Claudication; Rest Pain; Gangrene Due to Arterial Insufficiency; Other Postinfectious and Segmental Peripheral Neuralgia; Angina Pectoris; Postmastectomy Pain Syndrome (Chronic Nonmalignant); Late Postmastectomy Pain or Regional Carcinoma; Segmental or Intercostal Neuralgia; Chronic Pelvic Pain Without Obvious Pathology; Pain from Urinary Tract; Carcinoma of the Bladder; Lumbar Spinal or Radicular Pain after Failed

Spinal Surgery; Spinal Stenosis (Cauda Equina Lesion); Pain referred from Abdominal or Pelvic Viscera or Vessels Perceived as Sacral Spinal Pain; Femoral Neuralgia; and, Sciatica Neuralgia. Although the chronic pain model typically considers only one chronic pain indication dependent variable at a time, there can be chronic pain model embodiments that would consider at least one and up to many chronic pain indication simultaneously.

FIG. 9 shows a method for cleansing data such as patient indicia from potential data sources before the data is used in creating the chronic pain model. Often it is desirable to clean the data before the data is operated upon because data from various sources can have incompatible formats and data can contain errors. Data cleansing improves the reliability, accuracy and robustness of the chronic pain patient identification system.

FIG. 10 shows a block diagram for creation of the chronic pain model in the form of a chronic pain risk inference engine embodiment. The chronic pain risk model comprises a logic structure, weighted variables, and equations. Some embodiments of the chronic pain risk model can include Hosmer-Lemeshow Goodness of Fit Analysis to evaluate the appropriateness of patient indicia, and monitoring patient indicia for changes that can be used to update the patient mathematical expression. The chronic pain risk inference engine can operate on at least fifty dependent variables, at least thirty independent variables, and at least fifty equations. The chronic pain risk model can be mathematically represented as follows:

$$f(x) = b_0 + b_1(X_1) + b_2(X_2) + b_3(X_3) \dots b_i(X_i) \text{ where } b_0 \text{ is a beta weight constant; } b_1 - b_i \text{ are the beta weights for each corresponding variable; } X_1 - X_i \text{ are the significant variables identified from the model; and } f(x) \text{ is the resultant measure of the characteristic of interest, i.e., chronic pain score. This chronic pain risk model equation creates a line that represents the minimized average for the dataset that is the line of prediction for the dataset.}$$

FIG. 11 shows a block diagram of a chronic pain risk stratification levels embodiment;
FIG. 12 shows a table of some chronic pain risk stratification combinations embodiment; and,
FIG. 13 shows a block diagram of some chronic pain risk stratification levels embodiment;
The chronic pain patient risk stratification system classifies the broad population of potential chronic
5 pain patients into smaller, more manageable groups that have varying probabilities of exhibiting
characteristics of diseases, conditions, or health seeking behaviors of interest. For this chronic pain
management program a minimum of four levels are employed, each with a defined intervention
strategy. At each level, a minimum of two substrata are identified to further focus the defined
intervention strategies.

10 Level 1 (Harm reduction): Stratification is based on the probability (or risk) of
experiencing a pain episode for which health care is sought. Factors associated with this
probability are determined from statistical modeling and include demographic factors (age,
gender), job related factors (job descriptions or work related activities), and lifestyle factors
(leisure activities, weight, exercise behaviors).

15 Level 2 (Pain Stratification): This population subset is identified by the presence of
medical and/or non-medical indicia of pain. Stratification is based on the probability that the
pain episode will be limited (acute) or become chronic. Factors associated with this probability
are determined from statistical modeling and would include medical diagnoses (ICD-9-CM, ICD-
9-Procedure, and CPT-4 codes found in standard coding manuals), the circumstances of injury
20 (location, single/multiple injury site(s), length of initial treatment), job related factors (lost days
from work, presence of Workers' Compensation claim), demographic factors (age and gender),
legal issues (presence of legal counsel) and lifestyle factors (leisure activities, weight, exercise
behaviors).

Level 3 (Chronic Pain Treatment): This population subset is identified by the presence of medical and/or non-medical indicia of chronic pain. Stratification is based on the need for treatment. Those with low immediacy of treatment need may be monitored from a distance (watchful waiting); those with an intermediate treatment need will be referred for a next available care opportunity and those with high immediacy of treatment need will be referred for immediate treatment. Factors associated with treatment need are classified based on medical diagnoses (ICD-9-CM, ICD-9-Procedure, and CPT-4 codes found in standard coding manuals), the circumstances of injury (location, single/multiple injury site(s), length of initial treatment), treatment circumstances (severity of pain, frequency of treatment) or crisis (threat of suicide or other self-injury).

Level 4 (Care Management): This population subset is identified by the presence of medical and/or non-medical indicia of chronic pain. Stratification is based on the probability that there will be low or high utilization of health services and/or costs. Factors associated with this probability are determined from statistical modeling and would include medical diagnoses (ICD-9-CM, ICD-9-Procedure, and CPT-4 codes found in standard coding manuals), the circumstances of injury (location, single/multiple injury site(s), length of initial treatment), job related factors (lost days from work, presence of Workers' Compensation claim), demographic factors (age and gender), legal issues (presence of legal counsel), lifestyle factors (leisure activities, weight, exercise behaviors) and circumstances of treatment (multiple physicians, multiple forms of rehabilitative services, the presence of extended use of pharmaceutical agents and/or multiple pharmaceutical agents [polypharmacy]). There are at a minimum, 24 potential combinations (FIG. 12) or stratification categories possible under the initial model. Further refinement will occur and possible stratification combinations will increase as the model becomes "smarter".

FIG. 14 shows a Chi-Square Automatic Interaction Detection (CHAID) analysis of harm reduction (level 1) prophetic example embodiment; FIG. 15 shows a Chi-Square Automatic Interaction Detection (CHAID) analysis of pain stratification (level 2) prophetic example embodiment; FIG. 16 shows a Chi-Square Automatic Interaction Detection (CHAID) analysis of pain treatment (level 3) prophetic example embodiment; and FIG. 17 shows a Chi-Square Automatic Interaction Detection (CHAID) analysis of care management (level 4) prophetic example embodiment. The logic structure used to establish relationships between a dependent variable and the independent variable can be developed using a statistical technique such as Chi-Square Automatic Interaction Detection (CHAID) analysis, CART analysis, and the like. The logic structure defines a logical decision process to progressively reach greater certainty about potential chronic pain patients. The logic structure can be evaluated using a statistical technique such as Hosmer-Lemeshow Goodness of Fit Analysis, and the like. CHAID is well known in the art, is an exploratory analysis executed to examine relationships that may exist between a dependent variable and multiple categorical variables that may interact with one another. It is predicated upon the supposition the necessary data is available, and that it is possible to distinguish, within a given data set, between two or more variables known to exist and known to be important.

CHAID is applied to the chronic pain construct in the following manner. Existing relevant information believed to be related to pain are culled from the clinical literature and bolstered by expert medical opinion, and a set of independent variables is identified based on current knowledge. As new clinical literature becomes available, the logic structure can be modified to include the new information. When the CHAID analysis is properly executed in a

sequential fashion, the independent variables most clearly associated with the chronic pain measure will emerge.

The independent variables (predictors) are assessed to determine if splitting the sample based on these variables leads to statistically significant discrimination on the dependent measure. The most significant relationship defines the first split on the sample (called a branch or node). Then, for each group formed by the split, the remaining independent variables are assessed to determine which, if any, can further significantly discriminate on the subgroup. The end result (referred to as a terminal nodes) is a series of groups that are maximally different from one another on the dependent variable. At each step a statistical assessment is made to determine if a significant split into further subgroups can be made.

The length of the tree is the number of branches allowed to reach a terminal node. Tree length is set by the researcher and statistician based on decision rules. Based on the experience of the researcher, it has been determined that the model will continue branching until the variables found significant in differentiating the included population subsets establish nodes of $N \leq 15$ individuals. This analysis will identify variables for inclusion only if they are determined to be significant at the $p < 0.05$ level. It is assumed that incorporating several different sources of non-medical risk data (Patient Survey, Employer records, etc.) will provide the necessary precision. An alternative to CHAID is Classification Adjusted Regression Tree (CART) analysis. However, CART does not have the same efficiency in creating the buckets of patients.

The CHAID technique presents certain advantages for this analysis. It provides a means of detecting patterns in what is a complicated set of data. The maximum amount of data is used because missing values can be incorporated into the analysis. The analysis allows for a nominal level of measurement on the dependent variable and the independent variables. Finally, the

resultant model will emphasize strong results without over-capitalizing on chance occurrences because the many variables are considered at once in a step-wise fashion. Thus, CHAID is extremely useful in detecting data trends. In addition, it will allow formation of meaningful interaction terms, which will inform the estimation of probability in subsequent logistic regression analyses.

FIG. 18 shows a table with a prophetic logistic regression example. The weighted variables reflect greater relevance of certain direct medical indicia, indirect medical indicia, and non-medical indicia to the chronic pain indication. The weighted variables can be developed using a statistical technique to establish relationships between the dependent variable and independent variables such as logistic regression, discriminant analysis, and the like. Logistic regression is a form of statistical modeling appropriate for categorical outcome variables. The method examines the relationship between a categorical response, or dependent variable, and a set of explanatory, or independent variables. The results of logistic regression provide regression coefficients. The coefficients can be as simple as a single numerical value or as complex as an equation including known independent variables. After transformation, the regression coefficients can be interpreted as odds ratios describing the influence of various factors and the dependent variables. The logistic regression procedure provides odds ratios for independent variables as well as the significance level for each odds ratio. For example, the process could provide that employees with job types where heavy lifting is characterized as a major function of the job, are three times more likely to be chronic low back pain sufferers than employees with other job types. As with CHAID analysis, the many independent variables will be considered in a stepwise fashion, which allows for detection of the most explanatory of the variables. To be included in the logistic model variables must achieve a significance level of $p < 0.05$.

Because the dependent variable has only two possible values (either chronic pain is present or it is not), it is not correct to assume that the variable would be normally distributed in a sample of individuals. By transforming the variable using a logistic function, the variable is made to appear closer to a normal distribution than would otherwise be the case (the assumption of a normal distribution being essential to the use of a linear statistical procedure). Taking into account the logistic transformation, the mathematical equation (or logistic function) that results from analysis takes the form:

$$\text{Log} \frac{p}{1-p} = b_0 + b_1(X_1) + b_2(X_2) + b_3(X_3) + b_4(X_4) \dots b_i(X_i) \quad \text{where } p \text{ is probability; } b_0 \text{ is}$$

a beta weight constant; $b_1 - b_i$ is the beta weight for each corresponding variable; and $X_1 - X_i$ are the significant variables identified from the model, e.g., X_1 can be job type, X_2 can be gender and job satisfaction, and X_3 can be Drug Therapy, Number of Children and Gender. This logistic regression equation is further complicated by the potential interactions, described mathematically as follows: $b(X_1 \bullet X_2)$. An alternative to Logistic Regression is Discriminant Analysis.

Discriminant Analysis requires looking at extreme groups of patients. In order to find the most efficient group, the process requires a mix of extremes. Once logistic regression has been complete, equations can be generated.

Equations are generated to represent relationships between or among weighted variables to build a chronic pain inference engine. The chronic pain inference engine can operate on at least fifty dependent variables; at least thirty independent variables; and, at least fifty equations. The potential chronic pain patients are identified with a patient mathematical expression generated by the chronic pain inference engine operating on the patient indicia and the chronic

pain indication. After a potential chronic pain patient is identified with a mathematical expression, that potential chronic pain patient's patient indicia can be monitored for relevant changes and the potential chronic pain patient's mathematical expression can be updated to reflect those changes. The computer will generate odds ratios and related significance levels as an output. Interpretation of results is a simple exercise of examining the sign (the direction of the parameter estimate), the value of the odds ratio, and its significance level.

The number of equations generated can become quite large such as thousand and millions or equations associated with each chronic pain indication dependent variable, and currently there are 456 separate chronic pain indications. Due to the complexity and large number of equations, a computer is typically required to calculate the equations to produce a patient mathematical expression. A prophetic example of the number and complexity of equation generation follows. It is known that there are at least 456 different indications for chronic pain. Assume a predictive model that accounts for each of these 456 dependent variables. Further assume that there are currently a total of 32 identified indicia for chronic pain, adding the medical and non-medical

indicia together (this number will grow as more is learned about chronic pain). If the model is developed out to the fourth level of independent variable (X_4) the calculation is as follows:

Step	Equation Possibilities
1	Each indicia is considered individually: <i>32 total possibilities.</i>
2	Each indicia is crossed with every other indicia for a two-way interaction calculation: $32 \times 31 = 992$ <i>total possibilities.</i>
3	Each indicia is combined in a three-way interaction calculation: $32 \times 31 \times 30 = 29,763$ <i>total possibilities.</i>
4	Each indicia is combined in a four-way interaction calculation: $32 \times 31 \times 30 \times 29 = 863,040$ <i>total possibilities.</i>
5	Total possibilities are added together: <i>893,827 total possibilities.</i>
6	The model is run 456 different times with 893,827 possibilities for each of these 456 indications.
<i>* If a fifth independent variable is presented, the possibilities increase to: 25,058,947 total possibilities.</i>	

In addition to the complexity introduced by interaction terms, each time a new variable is identified and introduced into a model the logistic function must be regenerated. Any newly identified variable can dramatically affect the resultant model (the number of variables found to be significant, the value of the odds ratios found, and the directional relationship of the variables). New variables can be found to have significance when compared with previously tested variables and new variables can change the significance level of previously significant and non-significant variables or can change the way previous variables interact with either the new variable or previously identified variables. Thus as our knowledge of chronic pain expands, model generation must be revised, creating a dynamic knowledge opportunity limited only by our ability to identify and appropriately measure (both validly and reliably) additional variables and our ability to refine measurement of previously identified variables.

The potential complexity of chronic pain model can be seen from the following prophetic example. In the applied CHAID example, X_1 is "Job Type". If it is discovered that X_1 is "Injured Employee Retains an Attorney", every other independent variable is potentially altered. This alteration includes order of importance, clusters of importance, and even relevance in terms of predictability. If X_1 becomes "Injured Employee Retains an Attorney", X_2 could likely become "Unresolved Workers Compensation Claim". The weighted value of the cluster of these 2 indicia could be significantly higher than the cluster of the previous 2 indicia of "Job Type" and "Gender or Job Satisfaction". The potential patient indicia, their importance and weight, alone and in combination with others can be immense.

The Hosmer-Lemeshow Goodness of Fit tests the models and determines whether the variables chosen for the model were the best possible. Once the logistic model is determined, the Hosmer-Lemeshow Chi-Square statistic is calculated to assess the goodness of fit of the model. A non-significant value indicates an adequate goodness of fit. If the Hosmer-Lemeshow analysis indicates that there is not a good fit, then the conclusion drawn is that there are variables other than those identified for model inclusion that might better explain the concept being investigated. This is an indication that further identification of variables and data sources for those variables must be determined.

FIG. 19 shows a block diagram of applying categorization preferences to a patient mathematical expression embodiment. Potential chronic pain patient's can be categorized by first establishing categorization preferences that specify characteristics of patients desired to be categorized. The categorization preferences include patient categorization preferences, payer categorization preferences, employer categorization preferences, primary care physician categorization preferences, and specialist physician categorization preferences. The different

stakeholder categorization preferences can be interrelated. For example, a payer categorization preference can include a potential chronic patient preference that might indicate whether the potential chronic pain patient would be compliance with a physical therapy regimen. Some examples of categorization preferences for a patient can include a desire to be notified of being a potential chronic pain patient even though the other stakeholders categorization preferences do not identify the patient as a potential chronic pain patient, a desire to not be notified of being a potential chronic pain patient unless the other stakeholders would support treatment, a desire to not be notified under any circumstance of being a potential chronic pain patient. Some examples of categorization preferences for a payer include a desire to know if potential chronic pain patient reimbursement criteria are met and a desire to know whether the potential chronic pain patient special care program criteria are met. Some examples of categorization preferences for an employer can include a desire to know potential chronic pain patients who's job performance may be affected and potential chronic pain patients that can be efficiently treated. Some examples of categorization preferences for a primary care physician can include potential chronic pain patients that are suitable for treatment by the primary care physician and potential chronic pain patients that should be considered for referral to a specialist. Some examples of categorization preferences for a specialist physician can include potential chronic pain patients that are suitable for treatment by the specialist physician and potential chronic pain patients that should be considered for referral to a primary care physician.

The categorization preferences are calculated against each potential chronic pain patient's mathematical expression to identify relationships between the categorization preferences and each potential chronic pain patient's mathematical expression. Calculation of categorization

preference can range from simple search and find algorithms to complex statistical models such a modified chronic pain model.

The software assigns an alphanumeric score for each patient identified under the rules of the inference engine. The number score, based upon a 0-100% rating, relates to the level of predictive confidence that an appropriate candidate has been identified. Patients with a confidence rating of $\geq 85\%$ will be considered as potential chronic pain patients, and their names will be passed along to a primary care physician for an initial determination of program inclusion or exclusion. Patients with a lower than 35% rating will be excluded from further consideration. Patients with a score in the range of 35% - 85% will be held in the system for up to one year, and the receipt of new information could alter their score upward or downward - triggering program inclusion or exclusion.

Letter designations represent pain type, site, or etiology, as coded or described in the data, as well as any other rules-based, identifying characteristics or profiles of pain. For this reason, patients can receive more than one letter designation. For example, a patient suffering from chronic peripheral neuropathy would receive an "E" designation in following Patient Rating System Table. If the patient were also diabetic, he or she would also be designated as a "V". It should be noted that a patient's letter designation is subject to change, based upon the receipt of additional relevant data. If no such feature can be identified from the data query, the letter Z is assigned.

The following table lists the letter designations and explains the meaning of each designation. As system knowledge increases, this list will change through addition, deletion or modification.

Patient Rating System Table	
Designation	Definition
A	Cardiac (Anginal Pain)
B	Low Back
C	Cancer
D	Failed Back Surgery Syndrome
E	Peripheral Neuropathy
F	Head, Face or Mouth
G	Repetitive Motion Injury
H	Urinary Tract
I	Stump Pain
J	Central Pain
K	Complex Regional Pain Syndrome
L	Causalgia
M	Chronic Pelvic Pain
N	Arthritis
O	Post Herpetic Neurology
P	Osteoporosis
Q	Spinal Cord Injury
R	Sickle Cell Arthropathy
S	Heavy Smoker
T	Trauma
U	Heart Failure
V	Diabetic
W	Work-related Injury
X	Psychological Profile
Y	Addictions
Z	No Identified Characteristics

5 Once potential chronic pain patients are selected, the potential chronic pain patient's patient indicia can be monitored to detect changes that can affect whether the potential chronic pain patients remain potential chronic pain patients or are no longer potential chronic pain patients. The selected potential chronic pain patient's direct medical indicia, indirect medical

indicia, and non-medical indicia are monitored for changes and the patient's mathematical expression is updated based upon changes to the potential chronic pain patient's direct medical indicia, indirect medical indicia, and non-medical indicia.

FIG. 20 shows a block diagram of a method of sensitivity analysis of a chronic pain model embodiment, and FIG. 21 shows a block diagram of applying a sensitivity analysis model.

The method can begin by comparing the identified potential chronic pain patients with outside diagnosed chronic pain patient data to create a patient error list. The outside diagnosed chronic pain patient data would typically include diagnosis information such as laboratory test results, patient survey data, physiologic measures, the specific chronic pain indication, and the like.

Sources for outside diagnosed chronic pain patient data include medical claim data, medical charts, employer records, worker compensation records, and the like. The patient error list has an error assessment model applied to the patient error list to identify non-corresponding patient indicia that contributed to the errors. The non-corresponding patient indicia are typically the absence of one or more patient indicia or the inclusion of one or more extraneous patient indicia.

The non-corresponding patient indicia has a sensitivity analysis model applied to the non-corresponding patient indicia to identify potential patient indicia changes to reduce errors in identifying chronic pain patients. Examples of potential patient indicia changes include the addition of one or more relevant indicia or the exclusion of one or more extraneous patient

indicia. At least one patient indicia change is selected from the potential patient indicia changes for changing. Finally, the patient indicia are modified with at least one selected patient indicia change. The modified patient indicia typically improve accuracy of the method for new patients entered into the system because new patient indicia may be required. The modified patient can

improve the accuracy of the method for patients currently entered into the system particularly if patient indicia are excluded.

The chronic pain model weighted variables can also be modified in a manner similar to the patient indicia. The sensitivity analysis model is applied to the weighted variables to identify potential weighted variable changes to reduce errors in identifying chronic pain patients. At least one weighted variable change is selected from the potential weighted variable changes to apply to the weighted variables. The weighed variables are modified to reflect greater or lesser relevance of patient indicia to reduce errors in identifying chronic pain patients.

Prophetic Patient Examples

The following examples describe four people identified as potential chronic pain sufferers through application of a chronic pain condition management identification model, also embodied as a computer software product. The examples illustrate how these people are stratified through application of a stratification model, also embodied as a computer software product. The prophetic examples are used to illustrate just one of the many application of the chronic pain patient identification system and should not be read to limit application of the identification system.

Patient A is a 42 year male truck driver, diagnosed with lumbar spine injury (ICD-9-CM 724.8) within the past 3 months from the last date of service (See Figure 5, Item #1).

Pharmaceutical claims indicate that Patient A received a prescription for an Opiate (Percocet, 8 per day) and a Nonsteriodal (Feldene) both for ≥ 91 days within the past 120 days from the last day of service (See Figure 5, Item #15). Patient A is also a heavy smoker (two packs per day, 20 years).

Level 1 (Harm Reduction): Patient A describes his pain (patient survey) as a dull, throbbing and spiking pain, often times debilitating pain. Pain episodes often correspond to his travel schedule

(i.e. worse on trips over 1500 miles in duration). The patient's job type, age, education level (tenth grade), self-described pain assessment (high), and injury type (lumbar spine) put Patient A into the "high probability of a pain episode" category.

Level 2 (Pain Stratification): The pattern of chronic drug use exhibited by Patient A, as indicated by drug type, length of time and dosage levels; his overall non-medical indicia score (job type, addictive personality, dissatisfaction with work, heavy smoker); the type and duration of injury; leads to a "chronic pain" categorization.

Level 3 (Chronic Pain Treatment): Patient's pattern of drug use, the fact that he is a poor communicator with his provider, his job type, age, and overall score on the patient self-report data (high pain intensity score, low job satisfaction and poor family support) Plead to a categorization of "high need of treatment".

Level 4 (Care Management): The medical records indicate that Patient A has had 2 (unsuccessful) back surgeries. This, in addition to his job type and the fact that he is a smoker, leads to a high utilization or cost categorization. He will be particularly high cost patient due to his addictive personality profile and history of prescription drug use.

Patient B is a 45 year old male who was flagged by the identification model because he received a number of spinal procedures. Because Patient B was eventually excluded from the chronic pain patient candidate list, he was not stratified.

Patient C is a 46 year old heavy industry laborer disabled by low back pain for 5 months, and with a lumbar spine-related (ICD-9- CM 722.6) primary diagnosis.

Level 1 (Harm Reduction): Patient C's job classification, age, education level (ninth grade), combined with his pattern of emergency room visits, cause him to receive a "high probability" of pain episode categorization.

Level 2 (Pain Stratification): Patient C's self-report pain intensity - described as high and unbearable at times; the existence of an open workers' compensation claim (with an involved attorney); and a medical chart history indicating para-spinal, bilateral pain radiating to the buttocks; and causes a "chronic pain" categorization.

5 Level 3 (Chronic Pain Treatment): Patient C lacks adequate primary characteristics that would cause a high ranking (prescription drug history, poor communication with provider). However, Patient C's job type (heavy industry) and his self-reported pain description leads to a "medium treatment immediacy" categorization.

10 Level 4 (Care Management): Patient C has self-reported depression. In addition, his job type, and the fact that there is an open workers' compensation claim, with an attorney representative, cause a "high utilization or cost" categorization.

15 Patient D is a 38 year old female who recently gave birth to her second child. Level 1 (Harm Reduction): Patient D lacks the primary characteristics that would cause a "high probability" ranking. For example, she does not work in heavy industry, is not at a high-risk age, and she has a college degree. She therefore receives a "low probability" ranking, although a notation is made in her record indicating that she does significant lifting of her children. She also has the type of injury that could potential cause a higher classification (lumbar). This is an example of a patient who could later be re-classified if future data collection tips the scale toward a "high probability" re-classification.

20 Level 2 (Pain Stratification): Patient D's pain is clearly acute at this point in time. First, the records indicate that the pain was event triggered (pregnancy). The literature supports the fact that pregnancy creates or exacerbates certain pain indications (including lumbar spine), and also highlights the fact that pain often subsided or disappears post-pregnancy. Furthermore, no

pattern of chronicity has been established in the medical records (e.g. emergency room visits, hospitalizations, prescription drug use).

Level 3 (Chronic Pain Treatment): Patient D's self-reported moderate-to-high pain intensity ranking (7 out of 10), self-reported pain description (Very Intense, Throbbing, Shooting), and overall high patient survey score (75) places her in the "medium treatment immediacy need" category.

Level 4 (Care Management): Patient D's trigger point injections (CPT code 00630) and prescription for a short acting opiate (Tylenol 3), and Dantrium (a muscle relaxant, in combination with her lumbar spine diagnosis, place Patient D in a moderate utilization or cost category. (She would actually be ranked somewhere between the high and low end points of the model) Patient D is not yet considered "high utilization or cost" because her condition appears to be acute (although that categorization could change with time).

Thus, embodiments of a method and computer software product for stratifying potential chronic pain patients by risk are disclosed to permits earlier and more targeted intervention to treat chronic pain to improve patient health, reduce costs, and provide additional benefits. One skilled in the art will appreciate that the present invention can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the present invention is limited only by the claims that follow.